

STUDY INFORMATION

Title of Project: Effect of delorme resistance exercises versus treadmill training on locomotor abilities in cerebral palsy after Achilles tendon release (short title: Effect of Delorme Resistance Exercises Versus Treadmill Training in Cerebral Palsy)

Principal Investigator:

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1.0 Research Introduction

1.1 Purpose/Specific Aims

To determine the effect of delorme resistance exercises versus treadmill training on locomotor abilities in cerebral palsy children

A. Objectives

The current study highlights the effect of treadmill training as compared to DeLorme resistance exercises on locomotor activities in cerebral palsy child after Achilles tendon lengthening. The present study would add to the clinical knowledge of physical therapists by promoting the implementation of treadmill training and DeLorme resistance exercises for this prevalent pediatric neurodevelopmental disorder and adding data to compare the effectiveness of both interventions. The study would decrease the burden of disease among community and enhance the social participation of cerebral palsy children. This in turn would improve the quality of living of these disabling diseased children.

B. Hypothesis/ Research Questions

We hypothesized that delorme resistance exercises along with traditional therapy will be equally effective as compared to treadmill training plus traditional therapy on locomotor abilities among children with spastic cerebral palsy after Achilles tendon release

1.2 Research Significance

Cerebral palsy is defined as a cluster of non-progressive motion and posture disorder resulting from irreversible damage to immature brain. The neurological deficit related to Cerebral Palsy is irreversible, muscular fatigue, musculoskeletal limitations and pain are found to be contributory

factors in cerebral palsy children that may incorporate a decline in locomotion(1).Cerebral palsy is one of the most important source of disability among children and its incidence is almost 3.6 in thousand live births(2). Children with Cerebral Palsy presents with ambulatory difficulties. The attainment of independent and efficient locomotion is important for musculoskeletal growth and cardiopulmonary progress as well as for functional activities. Therefore, it is an essential aim of rehabilitation in these children(3).

Cerebral palsy children have frequent gait abnormalities secondary to development for which there is intense need for surgical corrections. Excessive Achilles tendon lengthening results in paresis of gastrosoleus and Achilles tendon that contribute to compromised locomotor abilities(4). The cerebral palsy children substitute the functional activities by utilizing alternate movement strategies. The development and persistence of compensatory patterns direct the goal of physical therapist towards minimizing these patterns. Thus ensuring improved muscle coordination and enhanced locomotor activities(5). Strength building resulting from DeLorme resistance exercises is significant for recurrence prevention and for enhancing the muscular performance(6).

Treadmill training is a fairly new approach that is utilized to efficiently train ambulation in Cerebral Palsy children. It stimulates repetitive stepping in an upright position with support, bearing weight on lower limb. It also enhances strength of lower extremity and improve balance reactions which aid in the locomotion process.(7)

The combined effect of treadmill and endurance training results in significant improvement in strength of muscles and prevents the recurrence of injuries as well as facilitates the rehabilitation. Therefore they play an important role in maintaining the functional capacity thus leading to improved fundamental activities of daily living. In addition, these resistive exercises along with

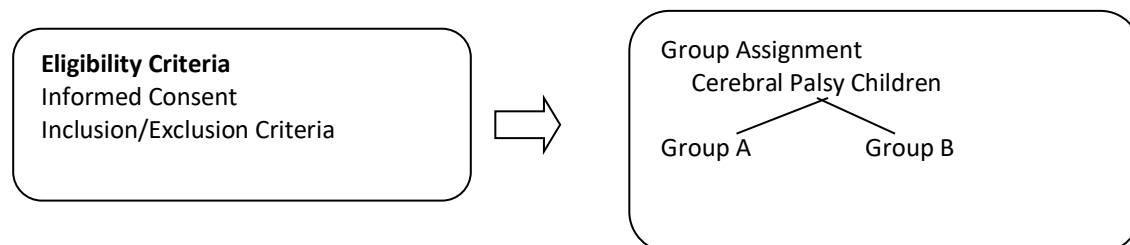
strength also improve balance of the cerebral palsy children ensuing increased social participation. Strength development resulting from these interventions enhances locomotor abilities of the child enabling them to play, work and perform daily life activities efficiently.

Insufficient evidences are available on treadmill training in pediatric population. The current study highlights the effect of treadmill training as compared to DeLorme resistance exercises on locomotor activities in cerebral palsy child. The present study would add to the clinical knowledge of physical therapists by promoting the implementation of treadmill training and DeLorme resistance exercises for this prevalent pediatric neurodevelopmental disorder. The study would decrease the burden of disease among community and enhance the social participation of cerebral palsy children. This in turn would improve the quality of living of these disabling diseased children.

1.3 Research Design and Methods

OVERVIEW

This is a single blinded Randomized Clinical trial to compare the effects of delorme resistance exercise versus treadmill training on locomotor abilities in spastic cerebral palsy children after Achilles Tendon Release. The study will be conducted at Dimensions Institute for Special Education and Psychological Services. There will be eligibility criteria and random assignment of participants to groups through simple random sampling.



RECRUITMENT

Children will be recruited from three different settings including 1 tertiary care hospital and two special schools. Consent will be taken from institution, guardians of the children and participants. Principal Investigator will provide an overview and basic purpose of the study. The final selection of the participants will be based on the eligibility criteria and participant willingness to participate in the study.

ELIGIBILITY SCREENING

Participants will be evaluated for eligibility screening. Informed consent will be taken from children and parents prior to eligibility process. A Member of research team will provide complete information, aim, objectives and importance of the project to parents and children. The baseline characteristics of children will be Gross Motor Functional Scale Level II and III and those with ability to understand commands and directions. Those children with Achilles Tendon lengthening procedure 3 to 6 months postoperatively will be included in the study and those who had never undergone treadmill training before. The diplegic type of cerebral palsy who had undergone bilateral Tendon of Achilles Lengthening will be recruited. The exclusion criteria will be subjects presenting with other types of CP, Children with audiovisual impairment that can hinder the treatment, leg length discrepancy greater than 2 cm, fixed contractures, joint instability and associated cardiovascular condition.

GROUP ASSIGNMENT

Upon confirmation of eligibility criteria, the Principal Investigator will randomly assign children to two equal groups namely Group A and B. Group A will receive treadmill training along with traditional physiotherapy and Group B will receive delorme resistance exercise with traditional physiotherapy

LOCOMOTOR ABILITY ASSESSMENT

Locomotor ability will be assessed using ABILOCO-kids questionnaire. It consisted of 10 locomotion activities of which difficulty was rated by the parents. It has good reliability $r=0.97$ and reproducibility of 0.96. Parent will be asked to fill in questionnaire by estimating their child's ease or difficulty in performing each activity. Activities will be presented in 10 different random orders to avoid any systematic effect. During evaluation, 3-level response scale will be presented to parent. Parent will be asked to rate his perception on response scale as 'Impossible', 'Difficult' or 'Easy'. Activities not attempted by child within last 3 months are not scored and are entered as not applicable. Activities that child doesn't perform because they are too difficult must be scored as 'Impossible'. **Child's locomotion ability** and its **95% confidence interval** are located on locomotion ability scale expressed in logits. Higher the ability of a child the more the measure will be located to the right.

1.4 Sample Size justification

The sample size is calculated by WHO Sample Size calculator keeping the level of significance as 5%, standard deviation as 4.35 and power of study kept at 90%.

1.5 Study Variables

A. Independent Variables, Interventions, or Predictor Variables

The independent variable will be treadmill training, delorme resistance exercise, cerebral palsy.

B. Dependent Variables or Outcome Measures

The outcome measure will be Locomotor abilities

1.6 Drugs/Devices/Biologics

N/A

1.7 Primary Specimen Collection

N/A

1.8 Interviews, Focus Groups, or Surveys

N/A

1.9 Time table of events

	July 2018	Aug 2018	Sep 2018	Oct 2018	Nov 2018	Dec 2018
Staff/student training, departmental setup, research material development						
Recruitment						
Eligibility screening and group assignment						
Testing						
Data analyses						
Write up, results dissemination and record archiving						

2.0 Project Management

2.1 Research Staff

Principal Investigator: Dr. Samreen Sadiq

Co-Investigator: Dr. Iqra Khan

Co- Investigator: Dr. Hafiz Asim

Co-Investigator: Dr. Amer Aziz

Co-Investigator: Dr. Samia Sarmad

2.2 Resources Availability

2.1 Facilities: Research will be conducted in Dimensions Institute for Special Education and Psychological Services. **It is equipped with modalities and treatment areas.**

2.2 Research Training: Principal Investigator **will complete the entire treatment process along with co investigator**

2.3 Multi-Site Research Communication & Coordination: N/A

3.0 Research Data Source/s

3.1 Primary Data-Subjects and Specimens

Male and female children

3.2 Subject Selection and Enrollment Considerations

A. Recruitment Details

Recruitment of participants was completed (received IRB approval). Participants were recruited through a special institute dimensions. Co investigator provided an overview of the study and described the broad selection criteria.

B. Subject Selection

Inclusion Criteria:

- Children with Gross Motor Functional Scale Level II and III
- Ability to understand commands and directions

- Diplegic type of cerebral palsy
- Children who had undergone bilateral Tendon of Achilles Lengthening procedure 3 to 6 months post-operatively

Exclusion Criteria:

- Children presenting with other types of Cerebral Palsy
- Children with audiovisual impairment that can hinder the treatment
- leg length discrepancy greater than 2 cm,
- Fixed contractures, joint instability and associated cardiovascular condition

3.3 Subject Randomization

Participants will be randomized through simple random number table. They will be assigned to Group A treadmill training plus traditional therapy and group B deLorme resistance exercise plus traditional therapy.

3.4 Secondary Subjects

N/A

3.5 Number of Subjects

A. Total Number of Subjects

50

B. Total Number of Subjects If Multicenter Study

N/A

C. Require Number of Subjects to Complete Research: 44

4.0 Bibliography

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